Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG

REF ODZ-496 | Σ 20 tests / cassette | 2°- 30 °C

Determination type: Antibody IgG (S1 RBD)
Evaluation type: Qualitative
Sample type: Human whole blood, serum and plasma

CE IVD

VIDIA

IVD

Rapid-VIDITEST
anti-SARS-CoV-2 (RBD) IgG

REF ODZ-496

Rapid chromatographic immunoassay for the qualitative detection of IgG antibodies against the receptor binding domain (RBD) of SARS-CoV-2 spike protein (S1) in human blood, serum and plasma samples

Instructions for use of the kit

Manufacturer: VIDIA spol. s r.o., Nad Safinou II 365, 252 50 Vestec, Czech Republic
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For professional in vitro diagnostic use only.

1. Use:

Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies against the receptor binding domain (RBD) of SARS-CoV-2 spike protein (S1) in human whole blood, serum and plasma samples. It is intended for use as an aid in the identification of individuals with an adaptive immune response to SARS-CoV-2. Positive results indicate the presence of IgG antibodies against SARS-CoV-2.

2. Introduction:

The novel coronavirus SARS-CoV-2 belongs to the genus of coronaviruses β. In humans, it causes an acute respiratory infectious disease called COVID-19. At present, the source of infection are patients infected with this coronavirus, even infected people who do not have symptoms of this disease, so-called asymptomatic patients. The main manifestations of COVID-19 are fever, fatigue and dry cough. In a few cases, a stuffy nose, runny nose, sore throat, myalgia and diarrhea occur, especially in young children.
All coronaviruses share similarities in the organization and expression of their genome, consisting of 16 nonstructural proteins (nsp1 to nsp16), encoded by an open reading frame (ORF) 1a / b at the 5 'end, followed by structural spike (S) proteins, a viral envelope (E), a membrane (M) and a nucleocapsid (N), which are encoded by other ORFs at the 3 'end.
The RBD protein (receptor binding domain protein) is part of the surface spike protein (S1 part) by which the virus specifically binds to the ACE 2 (angiotensin-converting enzyme 2) receptor of the host cell, especially the host respiratory epithelial cell, during infection. If specific IgG antibodies against the RBD protein of the coronavirus SARS-CoV-2 are present in the body (after vaccination with vaccines from different manufacturers and / or after infection), they may bind to the RBD domains of the virus. This blocks their ability to bind to the ACE 2 receptor and neutralizes the virus. Therefore, they are also called neutralizing antibodies.
The duration of the antibody response has not yet been confirmed, but it is known that the level of antibodies to other coronaviruses decreases over time (ranging from 12 to 52 weeks after the beginning of symptoms) and homologous reinfections have been demonstrated. In patients infected with SARS-CoV-1, 90 % of them were shown to persist IgG antibodies for two years and 50 % for three years.

Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG, due to the ongoing SARS-CoV-2 virus pandemic, is significantly used in the diagnosis of antibodies, as it allows monitoring the antibody response after infection and / or vaccination, i.e. allows to detect protective and neutralizing antibodies especially in high-risk groups of patients.

3. Principle of the test:

Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to the receptor binding domain (RBD) of SARS-CoV-2 Spike protein (S1) in a whole blood, serum or plasma sample. The anti-human IgG antibody is applied to the line in the test area. During testing, the sample reacts with SARS-CoV-2 RBD antigen coated particles in the test cassette. The mixture then rises up the membrane by capillary action and reacts with anti-human IgG antibody in the test area. If the sample contains IgG antibodies to SARS-CoV-2, a colored line will appear in the test area. If the IgG antibody sample does not contain SARS-CoV-2 RBD virus, no colored line will appear in the test area, indicating a negative result. As a check of the correct course of the test (the test is valid), a control line is used, which indicates that the correct volume of the sample has been added and that the sample has risen correctly by the membrane.

4. Material supplied with the kit:

- Test cassettes
- Buffer
- Droppers
- Sterile lancets (for whole blood from the finger)
- Alcohol swabs (for whole blood from the finger)
- Package leaflet

5. Required material not supplied with the kit:

- Stopwatch
- Sampling container (for serum or plasma test)
- Centrifuge
- Pipette

6. Measures:

1. This package leaflet must be read before performing the test. Failure to follow the instructions in the package leaflet may lead to inaccurate test results.
2. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
3. Do not eat, smoke or drink in areas where specimens or kit are handled.
4. Do not use the test if the packaging is damaged.
5. Treat all specimens as potentially infectious. Follow established precautions against microbiological hazards and follow standard procedures for proper sample handling.
6. Wear protective clothing such as a lab coat, disposable gloves, and goggles when testing specimens.
7. Wash your hands thoroughly after work.
8. Be sure to use the appropriate amount of sample for testing. Too small or large amounts can lead to variations in the result.
9. Used tests should be disposed of as infectious material.
10. Temperature and humidity may adversely affect the result.

7. Storage and stability:

Store packed in a closed container at room temperature or in a refrigerator (2-30 ° C). The test is stable until the expiration date stated on the package. The test must remain in a closed container until use. DO NOT FREEZE. Do not use after the expiration date.

8. Sampling and preparation of samples:

8.1. Sampling

Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG can be performed using whole blood (venous or finger collection), serum or plasma samples.

To take a whole blood sample from a finger:

1. Wash the patient's hand with soap and warm water and clean with an alcohol swab. Allow to dry.
2. Gently massage your fingers (middle finger or ring finger) towards the tip of the finger without touching the collection point.
3. Pierce the skin with a sterile instrument (lancet). Remove the first drops of blood
4. Gently rub the hand from wrist to palm and finger to get a round drop of blood over the injection site.
5. Transfer the blood sample from the injection to the test using a capillary.
6. Press the end of the capillary against a drop of blood and allow about 20 µl to be aspirated. Avoid sucking in air bubbles.

For a serum or plasma sample test:

1. Separate serum or plasma from whole blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
2. The test should be performed as soon as possible after sampling. Do not leave samples at room temperature for extended periods of time. Serum and plasma samples can be stored at 2-8 ° C for up to 7 days, for longer storage keep serum / plasma samples at -20 ° C. Store whole blood samples from a venous collection at 2-8 ° C if the test is performed within 2 days of collection. Do not freeze whole blood samples. Whole blood samples taken from a finger should be tested immediately.
3. Allow samples to reach room temperature before performing the test. Frozen samples must be completely thawed and mixed thoroughly before performing the test. Do not repeatedly thaw or freeze samples.
4. If samples are to be sent, they should be packaged in accordance with local regulations regarding the transport of infectious agents.

EDTA K2, Heparin, sodium citrate and potassium oxalate can be used as anticoagulants during sampling.

9. Instructions for use:

Allow the test, samples, buffer, and / or controls to reach room temperature (15-30 ° C) before performing the test.

1. Remove the cassette from its package and use it within one hour. For best results, perform the test immediately after opening.
2. Place the cassette on a clean, flat surface.

For serum and plasma samples:

- Transfer 10 µl of sample to the sample window (S) using a pipette or dropper (to the filling line), then add 2 drops of buffer (about 80 µl) and turn on the stopwatch.

For whole blood samples from a venous or finger collection:

- Transfer 20 µl of sample to the sample window (S) using a pipette or dropper (approx. 1cm above the filling line), then add 2 drops of buffer (approximately 80 µl) and turn on the stopwatch.

3. Wait for the colored lines to appear. Read the result in 10 minutes. Do not interpret results after more than 20 minutes.

Note: We recommend that you do not use the buffer for 6 months after opening the bottle.

10. Interpretation of results (see Fig.1):

POSITIVE: Two colored lines appear. One colored line must always appear in the control section (C) and the other line will appear in the test area T. A positive result in the test area indicates that the sample contains IgG antibodies against SARS-CoV-2 RBD virus.
* Note. The intensity of the test line (T) shade may vary depending on the concentration of IgG antibodies to SARS-CoV-2 RBD in the sample. Therefore, any indication of color in the test line should be considered a positive result.

NEGATIVE: One colored line appears in the control area (C) No colored line appears in the test line (T).

INVALID: The control line does not appear. The most common reasons for control line failure include insufficient sample volume or poor performance. Review your procedure and test with a new cassette. If the problem persists, stop using the kit and contact your distributor.

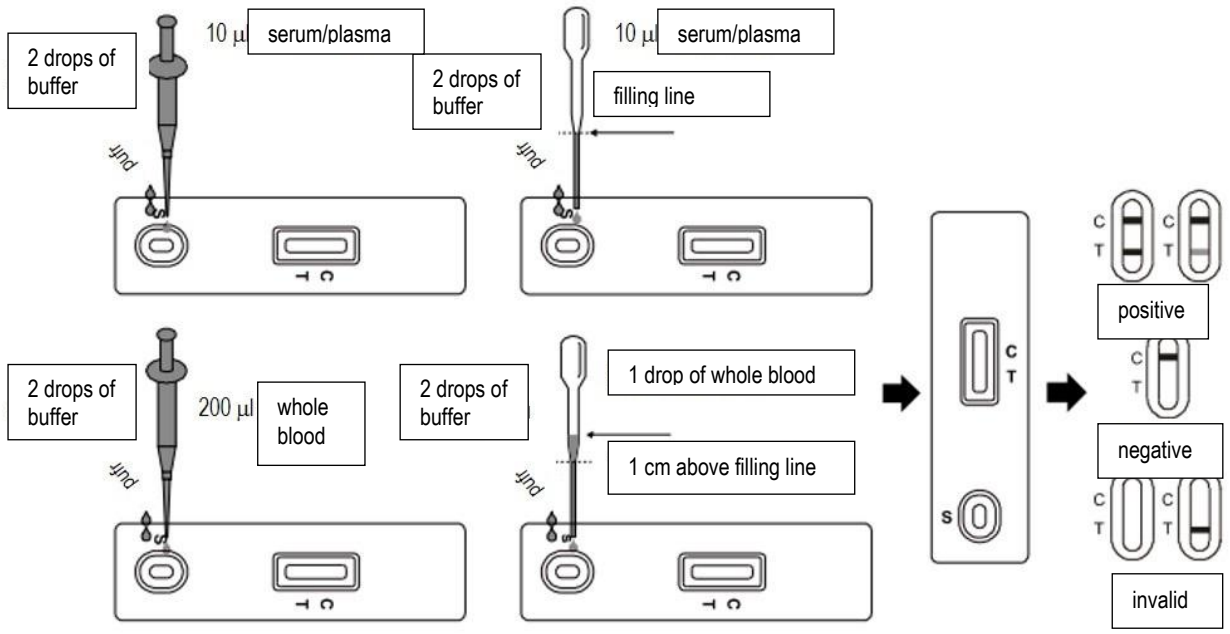

Fig. 1: *Interpretation of results*

11. Quality control:

The test includes internal process controls. The colored line appearing in the control area (C) is the internal process control. It confirms that the correct sample volume has been used and that the test has been performed correctly. Control standards are not supplied with this kit. It is recommended that positive and negative controls be tested as part of Good Laboratory Practice and to verify that the test is performed correctly.

12. Restrictions:

1. When testing for the presence of specific IgG antibodies against RBD virus SARS-CoV-2 Spike protein (S1) in a serum, plasma or whole blood sample from individual subjects, the Procedure and the Interpretation of the test result should be followed carefully. Proper sampling is essential for optimal test results. Failure to follow the procedure may lead to inaccurate results.
2. Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG is for *in vitro* diagnostic use only. This test is used to detect IgG antibodies against RBD virus SARS-CoV-2 Spike protein (S1) in whole blood, serum or plasma samples, as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection, in conjunction with clinical manifestations and the results of other laboratory tests. This qualitative test cannot determine the quantitative value or the rate of increase of the concentration of IgG antibodies against RBD virus SARS-CoV-2.
3. Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG indicates the presence of IgG antibodies against RBD virus SARS-CoV-2 in the sample and cannot serve as a separate criterion to confirm the diagnosis of SARS-CoV-2 infection.
4. As with other tests, all results must be considered together with other clinical information available to the doctor.
5. If the test result is negative and clinical signs persist, retesting several days later or performing a molecular diagnostic test is recommended to rule out infection in these individuals. A negative result does not rule out the presence of SARS-CoV-2 infection.
6. The hematocrit level in whole blood may affect the test result. For accurate results, the hematocrit level should be between 25% and 65%.
7. The test result will show a negative result under the following conditions: the antibody titre against the new coronavirus in the sample is lower than the minimum detection limit of the test, or the virus has undergone an amino acid mutation in the epitope recognized by the antibody used in the test, or the antibodies did not form yet at the moment of sampling (asymptomatic phase).
8. The persistent presence or absence of antibodies cannot be used to determine the success or failure of therapy.
9. Results from immunocompromised patients should be interpreted with caution.
10. Negative results do not rule out SARS-CoV-2 infection, especially in individuals who have been in contact with the virus. Subsequent testing with molecular diagnostics should be considered to rule out infection in these individuals.
11. Positive results may be due to past or current infection with coronavirus strains other than SARS-CoV-2 (e.g., HKU1, 229E, NL63, OC43) or other interference factors.
12. Not intended for screening of donated blood.

13. Test characteristics:

Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG was compared to a commercial ELISA assay, the results of which are shown below.

IgG results

Method		ELISA (RBD)		Total results
Rapid-VIDITEST SARS-CoV-2 (RBD) IgG	Result	Positive	Negative	
	Positive	184	4	188
	Negative	6	306	312

Total Resulst	190	310	500

Sensitivity: 96.8 % (95% IS*: 91,3% - 99,7 %) *Confidence Interval

Specifitu: 98,7 % (95% IS*: 94,6 % - 99,8 %)

Accuracy: 98% (95% IS*: 95,0 % - 99,5 %)

14. Accuracy:

Intraassay

The accuracy within the series was determined using 3 replicates of three samples: negative, 2 IgG positive, their values were correctly identified in> 99% of cases.

Interassay

The accuracy between tests was determined by 3 independent tests on the same three samples: negative, 2 IgG positive and three different batches of Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG for 3 consecutive days. Samples were correctly identified in> 99% of cases.

Interfering substances

The interference of the following substances with the results of the Rapid-VIDITEST anti-SARS-CoV-2 (RBD) IgG test was tested:

triglycerides: 100 mg / dl ascorbic acid: 20 mg / dl
haemoglobin: 1000 mg / dl bilirubin: 60 mg / dl
total cholesterol: 15 mmol / l
No interference was observed.

15. References:

- Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164. PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2
- Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502. PMID:27012512DOI:10.1016/j.tim. 2016.03.003

16. Symbols used:

IVD	Intended for in vitro diagnostics	Σ	Contains <n> tests
2°C 30°C	Store between 2-30 °C		Expiration
	Do not use if package is damaged	LOT	Batch number
	Manufacturer		Read the instructions for use
Σ	Contains <n> tests		Do not reuse
		REF	Catalogue number

sterile lancet

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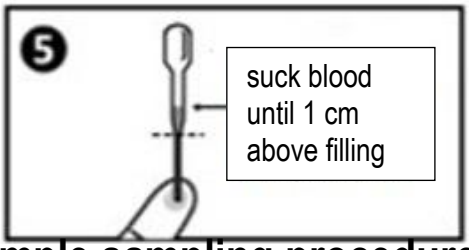
Taking a whole blood sample from a finger using a lancet and performing the test



Simple sampling procedure